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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,789	01/25/2002	Paul Haynes	NADII.022A	9365
25297	7590	05/04/2004	EXAMINER	
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/057,789	Applicant(s) HAYNES ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3 sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the paper filed February 6, 2004.

Applicant's election of the invention of Group I, claims 1-10, in the paper filed February 6, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election of species requirement set forth in the Office action mailed December 4, 2003 is hereby withdrawn. Claims 1-10 have been searched and examined in their entirety.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The Sequence Listing filed June 28, 2002 was not accompanied by a statement that the content of the paper and computer readable copies include no new matter as required by 37 CFR 1.821(g) and/or 1.825(a).

Correction is required.

The Sequence Listing filed June 28, 2002 was approved by STIC for matters of form.

3. The abstract of the disclosure is objected to because it is insufficiently detailed as to the basic structure of the compounds which form part of the elected invention. Correction is required. See MPEP § 608.01(b).

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4. The substitute specification filed June 28, 2002 is approved.
5. The disclosure is objected to because of the following informalities: A SEQ ID NO needs to be inserted into the Brief Description of Figure 2B, which recites an amino acid sequences subject to the sequence disclosure rules. See 37 CFR 1.821(d). Appropriate correction is required.
6. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The structures of the compounds being claimed is unclear. With respect to formulas (II) and (III) and the -NH-X- groups which are present, when X is an amino acid sequence, it is not clear if the sequence is oriented in the conventional direction, with the N-terminus on the left-hand side and resulting in the formation of a -NH-NH- group, or if the sequence is oriented with the C-terminus at the left-hand side so that a more conventional -NH-C(O)- bond results. For analogous reasons, it is not clear what structure the -Z-Link group in formulas (II) and (III) has when Z is one of the amide bond formulas. With respect to formula (II) and variable Y, it is not clear if the amide bond of formula -C(O)-NR- represents a group in addition to the carbonyl group which would be present at the end of the Epitope Tag Site and in addition to the amino group which would be present at the beginning of the Protease Cleavage Site. If so, then the compound of formula (II) could comprise a -C(O)-C(O)-NR-NH- group, which is not typical of most peptide compounds. Claim 1 recites that Link can be Arg- δ -iodoacetamide. However, the examiner can not find a structure for this compound either in the specification or in the prior art. If the " δ " is to be taken literally, then it would appear that the iodoacetamide group is reacted with the amino nitrogen directly attached to the -CH₂-CH₂-CH₂-

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group present in the arginine sidechain. It is not clear how such a sterically hindered arginine analog could be formed. Alternatively, the iodoacetamide group might be reacted with one of the amino nitrogen at the very terminus of the arginine sidechain. However, these are not typically referred to as δ atoms. Claim 1 requires Link to be Lys- ϵ -iodoacetamide, Arg- δ -iodoacetamide, or Orn- δ -iodoacetamide. However, claim 2 does not require the presence of such groups, but rather requires the presence of $-\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2\text{-NH-C(O)-CH}_2\text{I}$ or $-\text{CH}_2\text{CH}_2\text{CH}_2\text{-NH-C(O)-CH}_2\text{I}$ groups in addition to C-terminal lysine or ornithine residues. It seems clear that claim 2 intends these groups to be in addition to the sidechains of the lysine or ornithine residues, and does not intend to represent lysine and ornithine residues with modified sidechains, because the last compound recited in claim 2 requires a C-terminal ornithine residue (which has a three-carbon atom sidechain) and requires the presence of a 4-carbon atom $-\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2\text{-NH-C(O)-CH}_2\text{I}$ group. Because the specific examples of Applicants' compounds, e.g., those recited in dependent claims 2 and 10, do not appear to correspond with the generic formulas recited in independent claim 1, it is not possible to use the specific examples to determine how the generic formulas should be interpreted.

7. Claim 10 is objected to because of the following informalities: The compounds in claim 10 use the abbreviations "G", "A", and "V", which the examiner assumes are the single letter abbreviations for the amino acids glycine, alanine, and valine which can appear in the Z position of formula (III). Assuming this is so, the abbreviation "A" for alanine needs to be changed, because this abbreviation is already used in claim 1, formula (II). Applicants may wish to change the abbreviations "G" and "V" for consistency. Appropriate correction is required.

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8. Claims 2 and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The compounds of claim 2 do not appear to comprise a Lys- ϵ -iodoacetamide, an Arg- δ -iodoacetamide, or an Orn- δ -iodoacetamide group as required by the independent claim. The compounds of claim 10 do not appear to comprise an -NH- group adjacent to the acyl group as required by formula (III) set forth in the independent claim. The compounds of claim 10 do not comprise a Lys- ϵ -iodoacetamide, an Arg- δ -iodoacetamide, or an Orn- δ -iodoacetamide group as required by the independent claim. This objection is related to the rejection under 35 U.S.C. 112, second paragraph, set forth in section 6 above.

9. The examiner interprets the compounds of claim 2 as requiring an amino group adjacent to the Acyl group and in addition to the amino group which is present in the N-terminal cysteine residue. This interpretation is consistent with the “-NH-X-” which is present in formula (II) of claim 1. If this interpretation is incorrect, Applicants are required to inform the examiner so that the subject matter which is intended to be claimed can be clarified.

10. Claims 1-10 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/264,576 because the provisional application ‘576, under the test of 35 U.S.C. 112, first paragraph, does not disclose compounds in which X can be between 1 to 10 amino acids (note that the provisional application discloses between 10 to 30 amino acids), does not disclose Z being glycine, alanine, a synthetic amino acid, or γ -aminobutyric acid, does not disclose compounds having the structures recited in instant claim 2, and does not disclose compounds of formula (III).

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Claims 2 and 10 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/305,232 because the provisional application '232, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

Claims 1 and 3-9 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/305,232 because the provisional application '232, under the test of 35 U.S.C. 112, first paragraph, does not disclose compounds in which X can be between 1 to 10 amino acids (note that the provisional application discloses between 10 to 30 amino acids), and does not disclose Z being glycine, alanine, a synthetic amino acid, or γ -aminobutyric acid.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1 and 3-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Washburn et al (U.S. Patent Application Publication 2003/0068825). Washburn et al teach compounds having the same structures recited in Applicants' claims. See, e.g., paragraphs [0222] through [0286]. This includes structures in which X is an amide bond, a carbonyl, or an amino acid sequence of 10 amino acids.

The disclosure of Washburn et al relied upon in the above rejection is entitled under 35 U.S.C. 119(e) to the benefit of the filing date of Washburn et al's provisional application 60/305,169. See, e.g., page 57, line 1 - page 64, line 4, of the provisional application '169.

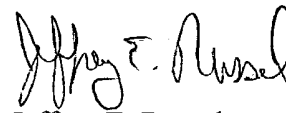
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Accordingly, Washburn et al has an earlier effective filing date than instant claims 1 and 3-9 (see section 9 above) and is available as prior art against these claims under 35 U.S.C. 102(e).

Washburn et al does not have an earlier effective filing date than instant claims 2 and 10 (see section 9 above), and accordingly is not prior art against these two claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 30, 2004